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EXAMINER
NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
1753	

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9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/844,929	KHAN, TAHIR S.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *03 December 2002* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Information Disclosure Statement

1. Bhullar et al. (EP 1195441) was cited as an "X" reference on the search report for EP 02254925, which was provided with the IDS of January 21, 2003. However, it does not disclose an electrochemical test strip having a plurality of reaction sites or "opposing working and reference electrodes separated by a spacer layer." Matzinger (WO 02/50609 A2), which was cited as a "Y" reference on the aforementioned IDS, can not be used in a prior art rejection because the US is not a designated state, as required by 35 U.S.C. 102(e). Furthermore, it had been assigned to the current assignees of the instant application at the time of the invention.

Drawings

2. The proposed drawing correction, filed on December 03, 2002 has been accepted. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Response to Amendment

3. Applicant's amendment of December 03, 2002 does not render the application allowable.

Response to Arguments

4. Applicant's arguments filed December 03, 2002 have been fully considered but they are not persuasive:

a) The rejections based on Schibli have been rewritten in light of the newly cited English language translation of EP 1167538 A1; and

b) Applicant has requested that all rejections involving Hodges et al. be withdrawn because the instant application and the Hodges et al. patent (US 6,413,410 B1) were allegedly commonly owned at the time of the invention. The examiner has not found support for this assertion. Although the examiner has not received Applicant's Notice of Recordation and Assignment Document, the amendment itself states recordation of ownership of the instant application occurred on July 16, 2002. This is after the time of the invention, which was April 24, 2001. Furthermore, to the examiner's best knowledge, common ownership of the instant application and the Hodges et al patent did not occur until August 27, 2002, the recordation date for the Hodges et al. patent, which is also after the time of invention to which the instant application is directed.

Status of Objections and Rejections Applied or Pending

Since the Office Action of September 11, 2002

5. The objection to claim 11 is withdrawn.

6. The objection to the drawings is withdrawn.

7. The rejection of Claim 17 under 35 U.S.C. §112, second paragraph, is withdrawn.

8. All previous prior art rejections are withdrawn.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 1, 2, 4, 8-12, 14, 17-19 are rejected under 35 U.S.C. 102(a) as being anticipated by newly cited English language translation of Schibli (EP 1167538 A1).

Addressing Claim 1, Schibli teaches an electrochemical test strip (the last line of page 2

bridging to the top paragraph of page 3) comprising

(a) a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer (Figure 1; last paragraph on page 4; fourth paragraph on page 13 ("Figure 1 ..."); and the first full paragraph on page 20) and

(b) a reagent composition present in at least one of the reaction zones, wherein at least one of the reagent compositions is a redox reagent system (third full paragraph on page 12).

Addressing Claim 2, at least two reaction zones are shown in Figure 1. Also note the last paragraph on page 4, which states, "practically any desired number of successive electrode pairs can be provided in the capillary channel."

Addressing Claim 4, having at least two different reagent compositions is disclosed in the top paragraph on page 10.

Addressing Claim 8, using enzyme with mediator is taught in the third full paragraph on page 20.

Addressing Claims 9 and 10, various oxidizing enzymes, including glucose oxidase, are taught in the second full paragraph on page 16.

Addressing Claims 11, 12, and 14; gold, platinum, and silver electrodes are disclosed in the second paragraph on page 17.

Addressing Claim 17, Schibli teaches a method of determining the concentration of an analyte in a physiological sample the method comprising

(a) applying the physiological sample to an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer and a reagent composition in each of the reaction zones (applying a physiological sample is implied by Claim 15 of Schibli, which teaches using the sensor to determine at least one blood value; the claimed plurality of reaction zones, spacer layer, and reagent compositions are taught in Figure 1; last paragraph on page 4; fourth paragraph on page 13 ("Figure 1 ..."); and the first full paragraph on page 20)

(b) detecting an electrical signal in the reaction zone using the opposing electrodes (implied by Claim 15 of Schibli, which teaches using the sensor to determine at least one blood value. Also see the third through fifth full paragraphs on page 20, which teach various electrical measurements that can be made); and

(c) relating the detected electrical signal to the amount of the analyte in the sample (the third paragraph on page 12 and Claim 15 disclose determining blood sugar, urea, lactate, and cholesterol, for example).

Addressing Claims 18 and 19, using glucose oxidase is taught in the second full paragraph on page 16. Also, see the third paragraph on page 12 and Claim 15, which disclose determining blood sugar.

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Schibli (EP 1167538 A1) in view of Yee (US 5,672,256).

Schibli teaches an electrochemical test strip (the last line of page 2 bridging to the top paragraph of page 3) comprising

(a) a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer (Figure 1; last paragraph on page 4; fourth paragraph on page 13 ("Figure 1 ..."); and the first full paragraph on page 20) and

(b) a reagent composition present in at least one of the reaction zones, wherein at least one of the reagent compositions is a redox reagent system (third full paragraph on page 12; second full paragraph on page 16; and third full paragraph on page 20).

Schibli appears to only disclose a different reagent composition in the various reaction zones. Yee teach having a plurality of electrochemical reaction zones each having the same reagent composition. See the abstract; Figures 3 and 4; and col. 4, ll. 22-28. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have the same reagent composition in the reaction zones as taught by Yee in the invention of Schibli because then a more accurate measurement can be obtained by averaging the measurements in the different reaction zones. See in Yee col. 2, ll. 44-57.

13. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Schibli (EP 1167538 A1) in view of Hodges et al. (US 6,413,410 B1).

Addressing Claim 13, Schibli teaches an electrochemical test strip (the last line of page 2 bridging to the top paragraph of page 3) comprising

(a) a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer (Figure 1; last paragraph on page 4; fourth paragraph on page 13 ("Figure 1 ..."); and the first full paragraph on page 20) and

(b) a reagent composition present in at least one of the reaction zones, wherein at least one of the reagent compositions is a redox reagent system (third full paragraph on page 12; second full paragraph on page 16; and third full paragraph on page 20).

Schibli does not disclose a volume range for the reaction zones in Schibli. Having reaction zones within Applicant's claimed range, barring evidence to the contrary, such as unexpected results, is just a matter of scaling down the test strip. As seen in Hodges et al. (col. 3, ll. 60-63) it was known at the time of the invention to have opposing electrodes closely spaced to form a cell having an effective volume of 1.5 μl.

Addressing Claim 15, Schibli teaches an electrochemical test strip (the last line of page 2 bridging to the top paragraph of page 3) comprising

(a) a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer (Figure 1; last paragraph on page 4; fourth paragraph on page 13 ("Figure 1 ..."); and the first full paragraph on page 20) and

(b) a reagent composition present in at least one of the reaction zones, wherein at least one of the reagent compositions is a redox reagent system (third full paragraph on page 12; second full paragraph on page 16; and third full paragraph on page 20).

Although palladium is not mentioned as an electrode material it is arguably within the scope of Schibli because he teaches several other precious metals. In any event, using electrodes made of palladium was known at the time of the invention, as seen, for example, in col. 9, ln. 62 – col. 10, ln. 9 in Hodges et al. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use palladium as the electrode material, for example, as taught by Hodges et al. in the invention of Schibli if this would optimize cost and desired conductance and corrosion resistance.

14. Claims 16, 20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Schibli (EP 1167538 A1).

Addressing Claim 16, Schibli teaches an electrochemical test strip (the last line of page 2 bridging to the top paragraph of page 3) comprising

(a) a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer (Figure 1; last paragraph on page 4; fourth paragraph on page 13 ("Figure 1 ..."); and the first full paragraph on page 20) and

(b) a reagent composition present in at least one of the reaction zones, wherein at least one of the reagent compositions is a redox reagent system (third full paragraph on page 12; second full paragraph on page 16; and third full paragraph on page 20).

Although Schibli does not mention having the strip present in a meter, it would have been obvious to one with ordinary skill in the art at the time the invention was made to do so because as seen from the fourth paragraph on page 13 the rear end of the strip is to be inserted into an analysis device.

Addressing Claim 20, Schibli teaches a method of determining the concentration of an analyte in a physiological sample the method comprising

(a) applying the physiological sample to an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer and a reagent composition in each of the reaction zones (applying a physiological sample is implied by Claim 15 of Schibli, which teaches using the sensor to determine at least one blood value; the claimed plurality of reaction zones, spacer layer, and reagent compositions are taught in Figure 1; last paragraph on page 4; fourth paragraph on page 13 ("Figure 1 ..."); and the first full paragraph on page 20)

(b) detecting an electrical signal in the reaction zone using the opposing electrodes (implied by Claim 15 of Schibli, which teaches using the sensor to determine at least one blood value. Also see the third through fifth full paragraphs on page 20, which teach various electrical measurements that can be made); and

(c) relating the detected electrical signal to the amount of the analyte in the sample (the third paragraph on page 12 and Claim 15 disclose determining blood sugar, urea, lactate, and cholesterol, for example).

Although Schibli does not mention having the strip present in a meter, it would have been obvious to one with ordinary skill in the art at the time the invention was made to do so because as seen from the fourth paragraph on page 13 the rear end of the strip is to be inserted into an analysis device.

Addressing Claim 24, Schibli teaches a system for use in determining the concentration of an analyte in a physiological sample (Claim 15), the system comprising

(a) an electrochemical test strip (the last line of page 2 bridging to the top paragraph of page 3) comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer (Figure 1; last paragraph on page 4; fourth paragraph on page 13 ("Figure 1 ..."); and the first full paragraph on page 20) and a reagent composition present in each of the reaction zones, wherein at least one of the reagent compositions is a redox reagent system (third full paragraph on page 12; second full paragraph on page 16; and third full paragraph on page 20).

Although Schibli does not mention having the strip providing a meter, it would have been obvious to one with ordinary skill in the art at the time the invention was made to do so because as seen from the fourth paragraph on page 13 the rear end of the strip is to be inserted into an analysis device.

15. Claims 21, 23, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Schibli (EP 1167538 A1) in view of Leader et al. (US 5,421,981).

Addressing Claim 21, Schibli teaches an electrochemical test strip (the last line of page 2 bridging to the top paragraph of page 3) comprising

(a) a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer (Figure 1; last paragraph on page 4; fourth paragraph on page 13 ("Figure 1 ..."); and the first full paragraph on page 20) and

(b) a reagent composition present in each of the reaction zones (third full paragraph on page 12 and second full paragraph on page 16).

Schibli does not mention providing a means for obtaining a physiological sample nor an analyte standard.

Leader et al. teach a kit for use in determining the concentration of an analyte in a physiological sample comprising a means for obtaining a physiological sample and an analyte standard. See the abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a means for obtaining a physiological sample and an analyte standard as taught by Leader et al. in the invention of Schibli because then the operator won't have to look for or store the appropriate analyte standard and means for obtaining the physiological sample. By having these items together in a kit, it is more convenient for whoever is going to use the test strip.

Addressing Claim 23, Although Schibli does not mention providing a meter it would have been obvious to one with ordinary skill in the art at the time the invention was made to do so because as seen from the fourth paragraph on page 13 the rear end of the strip is to be inserted into an analysis device.

Addressing Claims 25 and 26, Schibli teaches a system for use in determining the Concentration of an analyte in a physiological sample (Claim 15), the system comprising

(a) an electrochemical test strip (the last line of page 2 bridging to the top paragraph of page 3) comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer (Figure 1; last paragraph on page 4; fourth paragraph on page 13 ("Figure 1 ..."); and the first full paragraph on page 20) and a reagent composition present in each of the reaction zones, wherein at least one of the reagent compositions is a redox reagent system (third full paragraph on page 12; second full paragraph on page 16; and third full paragraph on page 20).

Although Schibli does not mention having the strip providing a meter, it would have been obvious to one with ordinary skill in the art at the time the invention was made to do so because as seen from the fourth paragraph on page 13 the rear end of the strip is to be inserted into an analysis device.

Schibli does not mention providing a means for obtaining a physiological sample nor an analyte standard.

Leader et al. teach a kit for use in determining the concentration of an analyte in a physiological sample comprising a means for obtaining a physiological sample and an analyte standard. See the abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a means for obtaining a physiological sample and an analyte standard as taught by Leader et al. in the invention of Schibli because then the operator won't have to look for or store the appropriate analyte standard and means for obtaining the physiological sample. By having these items together in a kit, it is more convenient for whoever is going to use the test strip.

16. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Schibli (EP 1167538 A1) in view of Leader et al. (US 5,421,981) as applied to Claims 21 and 23 above, and further in view of Guruswamy et al. (5,004,583). Schibli as modified by Leader et al. does not disclose a lance, although Leader et al. do disclose a syringe (col. 14, ll. 38-41).

Guruswamy et al. disclose that lances were used at the time of the invention to obtain small samples for test strips. See col. 1, ln. 65 – col. 2, ln. 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a lancet as taught by Guruswamy et al., instead of, or in addition to, a syringe in the invention of Schibli as modified by Leader et al. because then small samples, such as a drop of blood, can be easily obtained and applied to the test strip.

17. Claims 1, 2, 4-6, 8-20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 6,413,410 B1).

Addressing Claim 1, Hodges et al. teach an electrochemical test strip comprising

(a) a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer; and

(b) a reagent composition present in at least one of the reaction zones, wherein at least one of the reagent compositions is a redox reagent system.

See the abstract; Figures 5-11; col. 5, ll. 33-37; and col. 8, ll. 32-38.

Although Hodges et al. do not explicitly mention having reagent in each of the reaction zones, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Hodges et al. teach using the sensor to test levels of biochemicals other than glucose and of other chemicals. See col. 10, ll. 25-35.

Addressing Claim 2, at least two reaction zones are shown in Figures 5-11.

Addressing Claim 4, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use different reagent composition in order to test for different analytes.

Addressing Claim 5, an embodiment in which each reaction zone has its own ingress channel is disclosed in Figure 9 and 10 and in col. 7, ln. 63 – col. 8, ln. 2.

Addressing Claim 6, Figures 7 and 8 show an embodiment wherein at least two reaction zones have fluid ingress channels that merger to produce a single ingress channel to provide for fluid communication between the reaction zones and the external environment of the test strip.

Addressing Claims 8-10, 18, and 19, glucose oxidase dehydrogenase and ferricyanide are taught in col. 8, ll. 32-38.

Addressing claims 11, 12, 14, and 15, almost all of the possible electrode compositions claimed are disclosed in col. 9, ln. 62 – col. 10, ln. 10. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use gold or palladium, for example, because these metals have very good electrical conductivity and good corrosion resistance.

Addressing Claim 13, an effective cell volume of 1.5 μl is taught in col. 3, ll. 62-63.

Addressing Claims 16 and 20, a meter is implied by col. 3, ll. 52-59, which discloses coupling the test strip to means for applying an electric potential to the electrodes and a means for measuring current change with time.

Addressing Claim 17, Hodges et al. teach a means for determining the concentration of analyte in a physiological sample the means comprising

an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference metallic electrodes separated by a spacer layer and at least one reagent in a reaction zone.

See the abstract; Figures 5-11; and col. 5, ll. 33-37; and col. 9, ln. 62 – col. 10, ln. 10.

Although Hodges et al. do not explicitly mention having reagent in each of the reaction zones, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Hodges et al. teach using the sensor to test levels of biochemicals other than glucose and of other chemicals. See col. 10, ll. 25-35.

As for the claimed steps of applying a physiologic sample, detecting an electrical signal, and relating the electrical signal to amount of analyte in the sample, these may be found in col. 2, ll. 40-65.

Addressing Claim 24, Hodges et al. teach a system for use in determining the concentration of an analyte in a physiological sample, the system comprising

(a) an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer; and a reagent composition present in at least one of the reaction zones, wherein at least one of the reagent compositions is a redox reagent system; and

(b) a meter (implied by col. 3, ll. 52-59, which discloses coupling the test strip to means for applying an electric potential to the electrodes and a means for measuring current change with time).

See the abstract; Figures 5-11; col. 5, ll. 33-37; and col. 8, ll. 32-38.

Although Hodges et al. do not explicitly mention having reagent in each of the reaction zones, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Hodges et al. teach using the sensor to test levels of biochemicals other than glucose and of other chemicals. See col. 10, ll. 25-35.

18. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 6,413,410 B1) as applied to Claims 1, 2, 4-6, 8-20, and 24 above, and further in view of Yee (US 5,672,256). Hodges et al. appear to only disclose a different reagent composition in the reaction zones. Yee teach having a plurality of electrochemical reaction zones each having the same reagent composition. See the abstract; Figures 3 and 4; and col. 4, ll. 22-28. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have the same reagent composition in the reaction zones as taught by Yee in the invention of Hodges et al. because then a more accurate measurement can be obtained by averaging the measurements in the different reaction zones. See in Yee col. 2, ll. 44-57.

19. Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 6,413,410 B1) in view of Leader et al. (US 5,421,981).

Addressing Claim 21, Hodges et al. teach an electrochemical test strip comprising

(a) a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer; and

(b) a reagent composition present in at least one of the reaction zones.

See the abstract; Figures 5-11; and col. 5, ll. 33-37.

Although Hodges et al. do not explicitly mention having reagent in each of the reaction zones, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Hodges et al. teach using the sensor to test levels of biochemicals other than glucose and of other chemicals. See col. 10, ll. 25-35.

Hodges et al. do not mention providing a means for obtaining a physiological sample nor an analyte standard.

Leader et al. teach a kit for use in determining the concentration of an analyte in a physiological sample comprising a means for obtaining a physiological sample and an analyte standard. See the abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a means for obtaining a physiological sample and an analyte standard as taught by Leader et al. in the invention of Hodges et al. because then the operator won't have to look for or store the appropriate analyte standard and means for obtaining the physiological sample. By having these items together in a kit, it is more convenient for whoever is going to use the test strip.

Addressing Claim 23, a meter is implied by Hodges et al. in col. 3, ll. 52-59, which discloses coupling the test strip to means for applying an electric potential to the electrodes and a means for measuring current change with time.

20. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 6,413,410 B1) Leader al. (US 5,421,981) as applied to Claims 21 and 23 above, and further in view of Guruswamy et al. (5,004,583). Hodges et al. as modified by Leader et al. do not disclose a lance, although Leader et al. do disclose a syringe (col. 14, ll. 38-41).

Guruswamy et al. disclose that lances were used at the time of the invention to obtain small samples for test strips. See col. 1, ln. 65 – col. 2, ln. 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a lancet as taught by Guruswamy et al., instead of, or in addition to, a syringe in the invention of Hodges et al. as modified by Leader et al. because then small samples, such as a drop of blood, can be easily obtained and applied to the test strip.

21. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 6,413,410 B1) as applied to Claims 1, 2, 4-6, 8-20, and 24 above, and further in view of Leader et al. (US 5,421,981).

Hodges et al. do not mention providing a means for obtaining a physiological sample nor an analyte standard.

Leader et al. teach a kit for use in determining the concentration of an analyte in a physiological sample comprising a means for obtaining a physiological sample and an analyte standard. See the abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a means for obtaining a physiological sample or an analyte standard as taught by Leader et al. in the invention of Hodges et al. because then the operator won't have to look for or store the appropriate analyte standard and means for obtaining the physiological sample. By having these items together in a kit, it is more convenient for whoever is going to use the test strip.

22. Claims 1, 2, 4, 8-20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergkuist et al. (US 6,123,820) in view of Hodges et al. (US 6,413,410 B1).

Addressing Claims 1 and 8-10, Bergkuist et al. teach an electrochemical test strip comprising

a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer

See the abstract and Figures 2 and 3.

Bergkuist et al. do not explicitly mention having reagent in each of the reaction zones, although having an ionophore in each reaction zone is disclosed. See col. 6, ll. 23-30. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Bergkuist et al. disclose that the sensor may be employed to test for biochemicals such as glucose and lactate. See col. 8, ll. 34-41.

Bergkuist et al. disclose measuring glucose and lactate (col. 8, ll. 34-39), but no particular redox reagent system is disclosed. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a redox reagent system comprising, for example, glucose oxidase and a mediator, such as ferricyanide, to measure glucose in the invention of Bergkuist et al. because this redox reagent system was commonly used at the time of the invention to measure glucose. See col. 1, ll. 25-45.

Addressing Claim 2, at least two reaction zones are shown in Figures 2 and 3.

Addressing Claim 4, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use different reagent composition in order to test for different analytes.

Addressing Claims 11, 12, 14, and 15, the electrode composition in Bergkuist et al. are not known; however, Applicant's claimed possible electrode compositions were known at the time of the invention, as shown, for example, by col. 9, ln. 62 – col. 10, ln. 9 in Hodges et al. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use gold or palladium, for example, as taught by Hodges et al. in the invention of Bergkuist et al. because these metals have very good electrical conductivity and good corrosion resistance.

Addressing Claim 13, the volume of the reaction zones in Bergkuist et al. so they will be assumed to be outside Applicant's claimed range; however, barring evidence to eth contrary, such as unexpected results, having reaction zones within Applicant's claimed range is just a matter of scaling down the test strip. As seen in Hodges et al. col. 3, ll. 60-63 it was known at the time of the invention to have opposing electrodes closely spaced to form a cell having an effective volume of 1.5 μl.

Addressing Claims 16 and 20, a meter is implied by Bergkuist et al. in col. 3, ll. 5-12, which teaches coupling the test strip to a means for dispslaying the measurement results in human-readable form.

Addressing Claim 17, Bergkuist et al. teach a means for determining the concentration of analyte in a physiological sample the means comprising

an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer and at least one reagent in a reaction zone.

See the abstract and Figures 2 and 3.

Although Bergkuist et al. do not explicitly mention having reagent in each of the reaction zones, having an ionophore in each reaction zone is disclosed. See col. 6, ll. 23-30. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Bergkuist et al. disclose that the sensor may be employed to test for biochemicals such as glucose and lactate. See col. 8, ll. 34-41.

The electrode composition in Bergkuist et al. are not known; however, metallic electrode compositions were known at the time of the invention, as shown, for example, by col. 9, ln. 62 – col. 10, ln. 9 in Hodges et al. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use gold or palladium, for example, as taught by Hodges et al. in the invention of Bergkuist et al. because these metals have very good electrical conductivity and good corrosion resistance.

As for the claimed steps of applying a physiologic sample, detecting an electrical signal, and relating the electrical signal to amount of analyte in the sample, it would have been obvious to one with ordinary skill in the art at the time the invention was made to perform these steps because the purpose of the test strip is measuring the levels of substance in body fluid, such as blood. See col. 1, ll. 1-24.

Addressing Claims 18, and 19, although Bergkuist et al. disclose measuring glucose (col. 8, ll. 34-39), no particular redox reagent system is disclosed. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a redox reagent

system comprising glucose oxidase and a mediator, such as ferricyanide, to measure glucose in the invention of Bergkuist et al. because this redox reagent system was commonly used at the time of the invention to measure glucose. See col. 1, ll. 38-45.

Addressing Claim 24, Bergkuist et al. teach a system for use in determining the concentration of an analyte in a physiological sample, the system comprising

(a) an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer; and

(b) a meter (implied by Bergkuist et al. in col. 3, ll. 5-12, which teaches coupling the test strip to a means for displaying the measurement results in human-readable form).

See the abstract and Figures 2 and 3.

Although Bergkuist et al. do not explicitly mention having reagent in each of the reaction zones, having an ionophore in each reaction zone is disclosed. See col. 6, ll. 23-30. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Bergkuist et al. disclose that the sensor may be employed to test for biochemicals such as glucose and lactate. See col. 8, ll. 34-41.

Bergkuist et al. do not explicitly mention having reagent in each of the reaction zones, although having an ionophore in each reaction zone is disclosed. See col. 6, ll. 23-30. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Bergkuist et al. disclose that the sensor may be employed to test for biochemicals such as glucose and lactate. See col. 8, ll. 34-41.

Bergkuist et al. disclose measuring glucose and lactate (col. 8, ll. 34-39), but no particular redox reagent system is disclosed. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a redox reagent system comprising, for example, glucose oxidase and a mediator, such as ferricyanide, to measure glucose in the invention of Bergkuist et al. because this redox reagent system was commonly used at the time of the invention to measure glucose. See col. 1, ll. 25-45.

23. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bergkuist et al. (US 6,123,820) in view of Hodges et al. (US 6,413,410 B1) as applied to Claims 1, 2, 4, 8-20, and 24 above, and further in view of Yee (US 5,672,256). Bergkuist et al. teach having arrays of identical sensors in col. 10, ll. 1-13. In any event, Yee teach having a plurality of electrochemical reaction zones each having the same reagent composition. See the abstract; Figures 3 and 4; and col. 4, ll. 22-28. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have the same reagent composition in the reaction zones as taught by Yee in the invention of Bergkuist et al. as modified by Hodges et al. because then a more accurate measurement can be obtained by averaging the measurements in the different reaction zones. See in Yee col. 2, ll. 44-57.

24. Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergkuist et al. (US 6,123,820) in view of Hodges et al. (US 6,413,410 B1) and Leader et al. (US 5,421,981).

Addressing Claim 21, Bergkuist et al. teach an electrochemical test strip comprising

a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer.

See the abstract and Figures 2 and 3.

Although Bergkuist et al. do not explicitly mention having reagent in each of the reaction zones, having an ionophore in each reaction zone is disclosed. See col. 6, ll. 23-30. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Bergkuist et al. disclose that the sensor may be employed to test for biochemicals such as glucose and lactate. See col. 8, ll. 34-41.

Bergkuist et al. do not mention providing a means for obtaining a physiological sample nor an analyte standard.

Leader et al. teach a kit for use in determining the concentration of an analyte in a physiological sample comprising a means for obtaining a physiological sample and an analyte standard. See the abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a means for obtaining a physiological sample and an analyte standard as taught by Leader et al. in the invention of Bergkuist et al. as modified by Hodges et al. because then the operator won't have to look for or store the appropriate analyte standard and means for obtaining the

physiological sample. By having these items together in a kit, it is more convenient for whoever is going to use the test strip.

Addressing Claim 23, a meter is implied by Bergkuist et al. in col. 3, ll. 5-12, which teaches coupling the test strip to a means for displaying the measurement results in human-readable form.

25. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bergkuist et al. (US 6,123,820) in view of Hodges et al. (US 6,413,410 B1) and Leader et al. (US 5,421,981) as applied to Claims 21 and 23 above, and further in view of Guruswamy et al. (5,004,583). Bergkuist et al. as modified by Hodges et al. and Leader et al. do not disclose a lance, although Leader et al. do disclose a syringe (col. 14, ll. 38-41).

Guruswamy et al. disclose that lances were used at the time of the invention to obtain small samples for test strips. See col. 1, ln. 65 – col. 2, ln. 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a lancet as taught by Guruswamy et al., instead of, or in addition to, a syringe in the invention of Bergkuist et al. as modified by Hodges et al. and Leader et al. because then small samples, such as a drop of blood, can be easily obtained and applied to the test strip.

26. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergkuist et al. (US 6,123,820) in view of Hodges et al. (US 6,413,410 B1) as applied to Claims 1, 2, 4, 8-20, and 24 above, and further in view of Leader et al. (US 5,421,981).

Bergkuist et al. do not mention providing a means for obtaining a physiological sample nor an analyte standard.

Leader et al. teach a kit for use in determining the concentration of an analyte in a physiological sample comprising a means for obtaining a physiological sample and an analyte standard. See the abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a means for obtaining a physiological sample or an analyte standard as taught by Leader et al. in the invention of Bergkuist et al. as modified by Hodges et al. because then the operator won't have to look for or store the appropriate analyte standard and means for obtaining the physiological sample. By having these items together in a kit, it is more convenient for whoever is going to use the test strip.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola
March 8, 2003